GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:4300
ANSWERED ON:12.12.2016
Monitoring of Pharma Units
Vanaroja Smt. R.

Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether India and the European Union have agreed to jointly monitor pharma units in the country;
(b) if so, the details thereof;
(c) whether India has emphasised on interaction to address cultural differences and misunderstanding as these were often causes for regulatory actions; and
(d) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (INDEPENDENT CHARGE)
(SMT. NIRMALA SITHARAMAN)

(a & b) : CDSCO (Central Drugs Standard Control Organization), under the Ministry of Health and Family Welfare and European Union has no agreement to jointly monitor Pharma Unit in the Country. However, CDSCO is granting Written Confirmation certificate to Indian API (Active Pharmaceutical Ingredients) Manufacturer for export of API's to European Union countries. Further, CDSCO has signed MoU with UK, Medicines and Healthcare Products Regulatory Agency wherein, both Countries agreed to engage collaboratively as observers in Medical Product inspections conducted by both parties as mutually arranged.
(c & d) : For export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country.
Regulatory actions are required to be taken in case of non- compliances, with the regulatory provisions and not on cultural differences and misunderstanding. However, with increased interaction among the regulators on regular basis, an environment of better understanding is created.
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